MAY 3 1 2006

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K051104**

Applicant information:

Date Prepared:	May 22, 2006
Name:	**Lapis Lazuli International NV**
Address	Damsluisweg 48 1332 ED Almere The Netherlands
Contact Person:	Mark Berkouwer Executive Officer
Phone number:	+31 (0) 36 547 6020
US Firm:	MedVice Consulting, Inc.
Official Correspondent:	Mr. Martin Dalsing
Phone number:	(970) 243-5490
Fax number:	(970) 243-5501
Email address:	marty@FDApproval.com

Device Information:

Device Classification:	Class II
Classification Number:	LPN 886.5928
Classification Name:	Accessories, soft lens products Soft (hydrophilic) contact lens care products

Trade Name: **EYE SEE™ Multipurpose Contact Lens Solution**

Purpose of 510(k) Submission

NEW DEVICE ~

Lapis Lazuli International NV proposes to market and sell in United States interstate commerce, The **EYE SEE™ Multipurpose Solution**. Data supporting substantial equivalency to the predicate devices, performance, and safety & efficacy of the **EYE SEE™ Multipurpose Solution** is contained in this submission.

Device Description

The **EYE SEE™ Multipurpose Solution** is a sterile, isotonic, buffered, solution containing boric acid, sodium chloride, Hydroxypropyl Methylcellulose (HPMC) as a lubricant, poloxamer 407 as a surfactant, disodium edetate as chelating agent, purified water and preserved with polyhexanide.

The **EYE SEE™ Multipurpose Solution** is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

Intended Use

The **EYE SEE™ Multipurpose Solution** is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfecting, and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.

Description of Safety and Substantial Equivalence

Data to demonstrate all indications: daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfecting, and storage of soft (hydrophilic) contact lenses, of the **EYE SEE™ Multipurpose Solution** have been included in this submission.

A series of non-clinical and clinical studies were completed on this product. The following studies have been completed:

> Lens Compatibility: Lens compatibility studies were undertaken after cycling lenses in the solution. The results indicated that all soft (hydrophilic) contact lenses were compatible with the solution.

Cleaning Effectiveness: The cleaning efficacy of the solution was evaluated through the determination of the Critical Micelle Concentration. The surfactant concentrations are well above the CMC for the individual surfactants.

Microbial Testing: Disinfection effectiveness was evaluated according to the FDA guidance document. The results indicate satisfactory levels of disinfection efficacy. Preservative efficacy testing with rechallenge was evaluated. All results were satisfactory.

Toxicology Testing: A series of cytotoxicity and eye irritation studies were performed. In these studies there was no evidence of toxicity

Clinical Study: Following an approved FDA clinical protocol, a 60-subject, one-month clinical study has been conducted and results indicate that the solution is non-inferior to the predicate devices.

The **EYE SEE™ Multipurpose Solution** is substantially equivalent in terms of its actions and indications for use to the following predicate devices:

PREDICATE DEVICES ~

"Complete®" brand Multi-purpose solution by Advanced Medical Optics K030092
"NRC07" Multi-purpose solution by Bausch & Lomb K033854

The **EYE SEE™ Multipurpose, Contact Lens Solution** meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

SUBSTANTIAL EQUIVALENCY CHART

Substantial Equivalency	EYE SEE™ MULTIPURPOSE SOLUTION	COMPLETE BRAND MULTI-PURPOSE SOLUTION K030092	NRC07 MULTIPURPOSE SOLUTION K033854
Manufacture	**Lapis Lazuli International**	**Advanced Medical Optics**	**Bausch & Lomb**
INTENDED USE	The **EYE SEE™ MULTIPURPOSE SOLUTION** is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfecting, and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.	The **COMPLETE™ BRAND MULTIPURPOSE SOLUTION** is indicated for the care of soft hydrophilic contact lenses. Use this product as recommended by our eye care practitioner to: Chemically (NOT HEAT) Disinfect, Clean, Rinse, Store, Remove Protein	The **NRC07 MULTIPURPOSE SOLUTION** is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner
Active Ingredient	Hydroxypropyl Methylcellulose (HPMC)	Hydroxypropyl Methylcellulose (HPMC)	Hydranate (hydroxyalkylphosphonate)
Surfactant	poloxamer 407	poloxamer 237	poloxamer 407
Preservative	Polyhexanide 0.00015%,	Polyhexamethylene biguanide 0.0001%	Alexidine dihydrochloride (0.00045%).
Chelating Agent	Disodium edetate	Disodium edetate	Disodium edetate
Tears Simulation Additive	Sodium chloride Boric Acid	Sodium chloride Potassium chloride	Boric acid, Sodium chloride, Sodium phosphate
Lens Care Regiemn	Rub and Rinse	No Rub	No Rub
Sterility Claim	Sterile	Sterile	Sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2006

Lapis Lazuli International, NV
c/o Mr. Martin Dalsing
Official Correspondent
Medvice Consulting, Inc.
2214 Sanford Dr., Suite #B7
Grand Junction, CO 81505

Re: K051104
Trade/Device Name: EYE SEE™ Multipurpose Contact Lens Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: May 22, 2006
Received: May 23, 2006

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K051104

Device Name: EYE SEE™ Multipurpose Contact Lens Solution

INDICATIONS FOR USE:

EYE SEE™ Multipurpose Contact Lens Solution is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.

Prescription Use ____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) 21 CFR 801 Subpart C)

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K051104